

REMARKS

Applicants acknowledge the cordial personal interview held November 3, 2005 between Examiner Henley, Dr. Martin Gosmann, a representative of applicants' assignee, and applicants' undersigned counsel. The following remarks are respectfully submitted to reflect the discussion that took place at the interview.

By this amendment, claims 4 and 11 have been amended to more particularly point out and distinctly claim applicants' invention. Support for the amendments is found in the specification, *inter alia*, in the description of the clinical study procedure in paragraph [0033] on page 17 of the specification. Claims 7 and 10 have been canceled. Claims 4-6 and 11-24 are presented for further examination.

The present invention is a novel dosage regimen suitable for use as an emergency treatment to treat a patient suffering from a recent onset of atrial fibrillation (AFib) and convert the fibrillations to a normal heart sinus rhythm (NSR). The treatment regimen involves continuous infusion of a single dose of an effective amount of at least one 3,7-diazabicyclo[3,3,1]nonane compound in two phases such that in the first phase a first part of the continuously administered single dose is administered at a first rate, and in the second phase a remaining part of the continuously administered single dose is administered at a second, slower rate. As demonstrated by the clinical study results reported in the specification, this treatment regimen has been found to produce enhanced conversion of recent onset atrial fibrillation to normal heart sinus rhythm.

The rejection of claims 4-7 and 10-24 under 35 U.S.C. §103(a) over Schoen et al., U.S. 4,550,112; Schoen et al., U.S. 4,912,113; Schoen et al., U.S. 4, 324,732; Chiou et al., Journal of Clinical Pharmacology; Burgrii et al. Medline Abstract; Clemens, U.S. 6,026,817; and Hofmann et al., U.S. 6,790,463 is respectfully traversed.

The primary references merely disclose that it is known to use 3,7-diazabicyclo[3,3,1]nonane compounds to treat arrhythmias, but, as acknowledged in the Office Action, the primary references fail to disclose or suggest in any way the claimed treatment regimen.

The secondary references do not compensate for the failure of the primary references to disclose or suggest the claimed treatment regimen. Instead, the secondary references each relate to a distinctly different type of dosage regimen in which multiple doses are administered in series at periodic time intervals over an extended period of time with the initial dose being a priming dose and the subsequent doses being maintenance doses. This is not at all the same as administration of a single dose by continuous infusion in two phases as currently claimed. Moreover, there is absolutely no impetus or motivation which would lead a skilled worker to attempt to modify the dosage regimens of either the primary references or the secondary references to derive a treatment regimen in which a single dose is continuously administered in two phases at different rates. Even if a skilled worker were to attempt to combine the teachings of the cited references, the result would not correspond to the presently claimed invention, and the combination of references thus fails to make out a proper, *prima facie* case of obviousness. Applicants' claims therefore are respectfully submitted to define clearly over the state of the art represented by the cited references, and reconsideration and withdrawal of the obviousness rejection are respectfully requested.

The obviousness-type double patenting rejection of claims 4-7 and 10-24 over co-pending application no. 10/8894,364 in view of Chiou et al., Burgrii et al., Clemens and Hofmann et al. is likewise respectfully traversed. This rejection fails essentially for the same reasons as the §103 obviousness rejection discussed above. Neither the claims of the cited prior application, nor the secondary references, discloses or suggests treating recent onset atrial fibrillation by continuous infusion of a single dose of a 3,7-diazabicyclo[3,3,1]nonane compound in two phases at different rates as claimed. There is simply no reason why one skilled in the art would think to modify the distinctly different regimens of the cited documents in order to come up with a two-phase continuous administration as claimed. Thus, the required obviousness is not made out, and the obviousness-type double patenting rejection cannot stand.

The rejection of claims 11-15 under 35 U.S.C. §112, second paragraph, also is respectfully traversed. The rejection is premised on the notion that the use of the term "about" renders the claim indefinite. Applicants respectfully disagree. In the present claims the term "about" is used to define preferred time periods of administration. In this context, persons skilled in the art would understand that the effectiveness of the treatment regimen does not depend on absolutely precise adherence to the stated time intervals. Rather, a skilled worker would realize that substantial compliance with the stated time intervals would unquestionably provide effective treatment. This, in the context of the present invention, the use of the term "about" would be clearly understandable to a person skilled in the art. At the interview, Examiner Henley acknowledged that in the context claims 11-15, the use of the term "about" was not indefinite and agreed to withdraw this rejection.

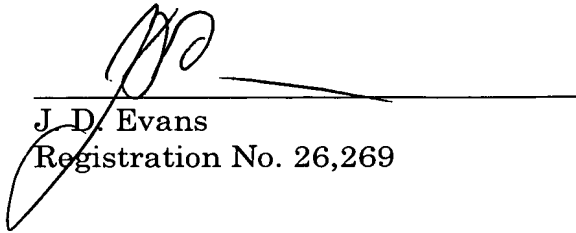
In view of the foregoing amendments and remarks, the application is respectfully submitted to be in condition for allowance, and prompt, favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned at (202) 624-2845 would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #029300.51815US).

Respectfully submitted,

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